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7	5/		Application	Serial Number	1	0/803,177	
(DEL 27 2004 (E)		Filing Date	· · · · · · · · · · · · · · · · · · ·	N	March 17, 2004	
1/3/			First Named Inventor		V	Wainwright	
TRANSMITTAL			Confirmatio	n No.	4	155	
		X1.7	Group Art U	Jnit	1	651	
	FORM		Examiner N	ame	١	lot yet assigned	
			Attorney Do	ocket No.	(CHR-004	
			Patent No.		N	lot applicable	
			Issue Date		N	lot applicable	
-		EN	CLOSURES (c	heck all that apply)			
☐ Fee	Transmittal Form		Copy of Notice	e to File Missing		Notice of Appeal to Board	
	☐ Check Attached		Parts of Applic	cation (PTO-1553)		of Patent Appeals and Interferences	
	Copy of Fee Transmittal Form		Formal Drawin	ng(s)		Appeal Brief (in triplicate)	
	Amendment/Response		Request For C			Status Inquiry	
	☐ Preliminary		Examination (I Transmittal	RCE)	}		
	After Final Affidavits/declaration(s)	Power of Attor				Return Receipt Postcard	
	Letter to Official					Certificate of First Class Mailing	
	Draftsperson including Drawings	☐ Terminal Disclain				Under 37 C.F.R.§1.8	
	[Total Sheets]			laimer		Certificate of Facsimile Transmission under 37 C.F.R. §1.8	
	Petition for Extension of Time		Copy of Executed Declaration and Power of Attorney for Utility or Design Patent Application			Additional Enclosure(s) (please identify below)	
	Information Disclosure Statement		Small Entity S	tatement			
	Form PTO-1449 Copies of Cited References (B1 and C1-C71)		CD(s) for large	e table or computer			
	Certified Copy of Priority		Amendment A	fter Allowance			
	Document(s)		Request for Ce	ertificate of			
	Sequence Listing submission Paper Copy/CD		Correction Certificate	of Correction (in			
	Computer Readable Copy		duplicate)				
	Statement verifying identity of above						
CORRI	ESPONDENCE ADDRESS	<u> </u>		SIGNATURE BL	оск		
Direct a	Il correspondence to: Patent Ad	ministrato	r			Respectfully submitted,	
Direct all correspondence to: Patent Administrator Testa, Hurwitz & Thibeault, LLP High Street Tower 125 High Street Boston, MA 02110 Tel. No.: (617) 248-7000 Fax No.: (617) 248-7100			Date: December 23, Reg. No. 51,752 Tel. No.: (617) 310- Fax No.: (617) 248-	-842 3	Jenniter G. Moitoso Attorney for the Applicants		



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS:

Wainwright et al.

CONFIRMATION NO.: 4155

SERIAL NO.:

10/803,177

GROUP NO.: 1651

FILING DATE:

March 17, 2004

EXAMINER: Not yet assigned

TITLE:

METHODS AND COMPOSITIONS FOR THE DETECTION OF

MICROBIAL CONTAMINANTS

CERTIFICATE OF FIRST CLASS MAILING UNDER 37 C.F.R. 1.8

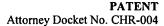
I hereby certify that this correspondence, and any document(s) referred to as enclosed herein, is/are being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 23rd day of December, 2004.

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Submitted herewith are:

- 1. Transmittal Form (1 pg.);
- 2. Information Disclosure Statement (2 pgs.);
- 3. Form PTO 1449 (9 pgs.);
- 4. Copy of Cited References (B1 and C1-C71); and
- 5. Return Receipt Postcard.





IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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METHODS AND COMPOSITIONS FOR THE DETECTION OF

MICROBIAL CONTAMINANTS

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. In accordance with the U.S. Patent Office's partial waiver of the requirement under 37 C.F.R. 1.98(a)(2)(i), only copies of the foreign patent documents and non-patent publications are enclosed.

REMARKS

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

	(1)	within three (3) months of the filing date of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the date of entry of the national stage as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the first Office action on the merits, or before the mailing of a first Office action after the filing of a request for continued examination under 37 C.F.R. 1.114; or
	(2)	after the period defined in (1) but before the mailing date of a final action or a notice of allowance under 37 C.F.R. 1.311, and
		the requisite Statement is below, OR
٠		the requisite fee under 37 C.F.R. 1.17(p), namely \$180.00, is included herein, or

Information Disclosure Statement Serial No. 10/803,177 Page 2 of 2

	(3)		the mailing date of a final action or notice of allowance but before the payment e issue fee, AND
		the re	equisite Statement is below, AND
		the re	equisite petition fee under 37 C.F.R. 1.17(p), namely \$180.00 is included herein.
	•	•	quested that each of the patents and publications listed on the attached Form formation contained herein, be made of record in this application.
			STATEMENT ,
	-		37 C.F.R. 1.97(e), Applicant(s), through the undersigned, hereby state either that
-		-	space only if either (2) or (3) is checked on the previous page <u>and</u> the
Stateme	ent is re	quireaj	
1			Each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the Information Disclosure Statement; or
			No item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this Statement after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.
Date: D Reg. No			Respectfully submitted, Jennifer G. Mortoso Attorney for the Applicants Testa, Hurwitz, & Thibeault, LLP

Tel. No.: (617) 310-8423 Fax No.: (617) 248-7100

High Street Tower 125 High Street

Boston, Massachusetts 02110

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FORM PTO – 1449

ATTORNEY DOCKET NO.: CHR-004

APPLICANT(S): Wainwright et al.

INFORMATION DISCLOSURE STATEMENT

SERIAL NO.:

10/803,177

FILING DATE:

March 17, 2004

GROUP:

1651

EXAM. INIT.	!	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A1	3,915,805	10/28/75	Levin			
	A2 _	3,944,391	3/16/76	Harris et al.			
	A3	3,954,663	05/04/76	Yamamoto et al.			
	A4	4,038,029	7/26/77	Teller et al.			-
	A5	4,038,147	7/26/77	Reno			
	A6	4,221,865	9/9/80	Dubczak et al.			
	A7	4,221,866	9/9/80	Cotter			
	A8	4,245,044	1/13/81	Kuo et al.			
	A9	4,273,557	6/16/81	Juranas			
	A10	4,279,774	7/21/81	Lindsay et al.			
	A11	4,301,245	11/17/81	Lindsay et al.			
	A12	4,322,217	3/30/82	Dikeman			
	A13	4,370,413	1/25/83	Neeman et al.			
	A14	4,376,819	3/15/83	Brown et al.			
	A15	4,606,824	8/19/86	Chu et al.			
	A16	4,717,658	1/5/88	Michaels			
	A17	4,806,316	2/21/89	Johnson et al.			
	A18	5,155,032	10/13/92	Tanaka et al.			
	A19	5,179,006	1/12/93	Matuura et al.			
· · -	A20	5,266,461	11/30/93	Tanaka			
	A21	5,286,625	2/15/94	Tanaka et al.			
	A22	5,310,657	5/10/94	Berzofsky			
	A23	5,316,911	5/31/94	Baek et al.			
 -	A24	5,318,893	7/7/94	Matuura et al.			
	A25	5,389,547	2/14/95	Tanaka et al.			

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U.S. PATENT DOCUMENTS

EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A26	5,372,946	12/13/94	Cusak et al.			
	A27	5,401,647	3/28/95	Tanaka et al.			
	A28	5,474,984	12/12/95	Tanaka et al.			
	A29	5,504,011	4/2/96	Gavin et al.			
	A30	5,518,006	5/21/96	Mawhirt et al.			
	A31	5,534,226	7/9/96	Gavin et al.			
	A32	5,550,030	8/27/96	Tanaka et al.			
	A33	5,574,023	11/12/96	Shibata et al.			
<u> </u>	A34	5,591,403	1/7/97	Gavin et al.			
	A35	5,591,628	1/7/97	Back et al.			
	A36	5,605,806	2/25/97	Tanaka et al.			
	A37	5,637,474	6/10/97	Tanaka et al.			
	A38	5,681,710	10/28/97	Tanaka et al.			
	A39	5,695,948	12/9/97	Tanaka et al.			
	A40	5,731,212	3/24/98	Gavin et al.			
	A41	5,702,882	12/30/97	Tamura et al.			
	A42	5,795,962	8/18/98	Iwanaga et al.			
	A43	5,800,781	9/1/98	Gavin et al.			
	A44	5,836,360	11/17/98	Gavin et al.			
<u></u>	A45	6,046,021	4/4/00	Bochner			
	A46	6,270,982	8/7/01	Jordan et al.		-	
	A47	6,303,389	10/16/01	Levin et al.			
	A48	6,391,570	5/21/02	Jordan et al.			
	A49	6,428,971	8/6/02	Shinabarger et al.			
	A50	6,440,722	8/27/02	Knapp et al.			·
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	A51	6,451,610		9/17/02	Go	rman <i>et al</i> .				
	A52	6,696,261		2/24/04	Pat	el <i>et al</i> .				
	A53	Des. 258,144		2/3/81	Ka	llet et al.				
	A54	Des. 278,182		3/26/85	Ail	nara <i>et al</i> .				
	A55	Des. 325,090		3/21/92	Ka	rp et al.				
	A56	Des. 330,428		10/20/92	Lev	wis <i>et al</i> .				
	A57	Des. 342,793		12/28/93	Bal	lmer				
	A58	Des. 343,905		2/1/94	Na	gata <i>et al</i> .				
	A59	Des. 353,676		12/20/94	Ke	lln <i>et al</i> .				
	A60	Des. 380,555		7/1/97	Ku	rosaki <i>et al</i>				
	A61	Des. 390,661		2/10/98	Fog	ggia				
	A62	Des. 391,373		2/24/98	Sha	artle				
	A63	Des. 437,419 S	S	2/6/01	Kra	ack et al.				
	A64	Des. 445,909 S	8	7/31/01	Pog	gorzelski				
	A65	Des. 463,570		9/24/02	Bee	dingham <i>et</i>	al.			
	A66	Des. 472,324		3/25/03	Ru	more et al.				
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	Cl	Aono et al., "In Spiny Lobster,			-					agulation in the 305 (1996).
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			APPLICANT(S): Wain	wright <i>et al</i> .			
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			FILING DATE: March	17, 2004			
			GROUP: 1651				
···	-	OTHER ART, JOUR	NAL ARTICLES, ETC.				
EXAM. INIT.	ОТН	ER DOCUMENTS: (Including Author, Tit	e, Date, Relevant Pages, Plac	e of Publication)			
	C2	Asokan et al., "Activation of Prophenoloxid viridis Linnaeus," Developmental and Comp					
	С3	Aspan et al., "cDNA cloning of prophenologits activation," Proc. Natl. Acad. Sci. USA, V					
	C4	Aspan et al., "The Effect of Endogeneous Proteinase Inhibitors on the Prophenoloxidase Activating Enzy A Serine Proteinase from Crayfish Haemocytes," <i>Insect Biochem</i> , Vol. 20, No. 5, pp. 485-492 (1990).					
	C5	Bettencourt et al., "Hemolymph-Dependent and –Independent Responses in <i>Drosophila</i> Immune Tissue Journal of Cellular Biochemistry, 92:849-863 (2004).					
	C6	Bullis, "Invertebrate Pathology: Responses to Injury and Disease," Aquavet II, Comparative Pathology of Aquatic Animals, Laboratory for Marine Animal Health, School of Veterinary Medicine, University of Pennsylvania, undated.					
	C7	Burmester <i>et al.</i> , "Origin and evolution of ar 172: 95-107 (2002).	hropod hemocyanins and related	ed proteins," J Comp Physiol B			
	C8	Charles River Laboratories, "In Vitro Pyrogo	n Test (IPT)," (2002).				
	C9	Charles River Laboratories, "IPT Assay Step	s, " (2002).				
	C10	"Comparative Immunology," Department of http://www.jamfys.ebc.uu.se/propo.html , pri		psala University,			
	C11	Cooper et al., "The Impact of Non-endotoxic Analyses," PDA Journal of Pharmaceutical 1997).					
	C12	Datta et al., "Purification of a unique glycop (Heterometrus bengalensis) haemolymph," I					
	C13	Decker et al., "SDS-induced Phenoloxidase Activity of Hemocyanins from Limulus polyphemus, Eurypelmic californicum, and Cancer magister," The Journal of Biological Chemistry, Vol. 276, No. 21, pp. 17796-17799 (May 2001).					
	C14	Decker et al., "Tarantula Hemocyanin Show Vol. 279, No. 40, pp. 25889-25892 (Octobe		Journal of Biological Chemistry,			
	C15	De Kimpe et al., "The cell wall components act in synergy to cause shock and multiple o					
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FORM I	PTO –	1449	ATTORNEY DOO	CKET NO.: CHR-004			
			APPLICANT(S):	Wainwright et al.			
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		OTHER ART, JOUR	NAL ARTICLES,	ETC.			
EXAM. INIT.	ОТН	ER DOCUMENTS: (Including Author, Tit	le, Date, Relevant Pag	ges, Place of Publication)			
	C16	Duner, Kristina I., "A new kinetic single-stagendotoxin in water and plasma," <i>Journal of I</i> (1993).	-	-			
	C17	Gollas-Galvan et al., "Prophenoloxidase from Comparative Biochemistry and Physiology I	• •	The state of the s			
	C18	Ganguly et al., "Tyrosine Phosphorylation of a 94-kDa Protein of Human Fibroblasts Stimulated by Streptococcal Lipoteichoic Acid," <i>The Journal of Biological Chemistry</i> , Vol. 260, No. 24, pp. 13342-1334 (October 1985).					
	C19	Geng et al., "Hemostasis in Larvae of Manduca Sexta: Formation of A Fibrous Coagulum by Hemolymph Proteins," Biochemical and Biophysical Research Communications, Vol. 155, No. 2, pp. 1060-1065 (September 15, 1998).					
	C20	Ginsburg, "Role of lipoteichoic acid in infec pp. 171-179 (March 2002).	tion and inflammation	", The Lancet Infectious Diseases, Vol. 2,			
	C21	Goldsworthy et al., "Adipokinetic hormone activation of the prophenoloxidase cascade i <i>Insect Physiology</i> , 48: 601-608 (2002).					
	C22	Halwani et al., "Apolipophorin-III and the In Responses of Galleria mellonella," Journal					
	C23	Hamada et al., "Chemical Properties and Impabl. Bakt. Hyg. A 259, 228-243 (1985).	munobiological Activi	ties of Streptococcal Lipoteichoic Acids,"			
	C24	Harrington et al., "Synthesis of Peptidoglyca Electrochemical Proton Gradient," Journal of					
	 C25 Hauton et al., "Circatidal rhythmicity in the activity of the phenoloxidase enzyme in the common shore Carcinus maenas, Comp. Biochem. Physiol. Vol. 111B, No.3, pp. 347-352 (1995). C26 Hauton et al., "In Situ Variability in Phenoloxidase Activity in the Shore Crab, Carcinus maenas (L.)," Biochem. Physiol. Vol. 117B, No.2, pp. 267-271 (1997). 						
C27 Hernandez-Lopez et al, "In the spiny lobster (Panulirus interruptus) the prophenoloxidase is located in plasma not in haemocytes," Fish & Shellfish Immunology, 14, 105-114 (2003).							
	C28	Hurley, James C., "Endotoxeima: Methods of Reviews, Vol. 8, No. 2, pp. 261-292 (April 1		al Correlates," Clinical Microbiology			
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FORM	PTO –	1449	ATTORNEY DOO	CKET NO.: CHR-004		
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EXAM. INIT.	ОТН	ER DOCUMENTS: (Including Author, Tit	le, Date, Relevant Pag	ges, Place of Publication)		
	C29	Iwanaga et al., "Chromogenic Substrates for of Bacterial Endotoxins," Hemostasis, Chap.				
,	C30	Iwanaga, Sadaaki, "The limulus clotting read Vol. 5, No. 5, pp. 74-82 (1993).	ction," Current Opinio	n in Immunology, Current Biology Ltd.,		
	C31	Iwanaga, "The molecular basis of innate imn Opin Immunol, Vol. 14, pp. 87-95 (2002).	nunity in the horseshoo	e crab," Curr		
	C32	Jiang et al., "Characterization and Functional Analysis of 12 Naturally Occurring Reactive Site Variants of Serpin-1 from Manduca sexta -," The American Society for Biochemistry and Molecular Biology, Inc., Volume 272, No. 2, pp. 1082-1087 (January 1997).				
	C33	Jiang et al., "Pro-phenol oxidase activating proteinase from an insect, Manduca sexta: A bacteria-inducible protein similar to Drosophila easter," Biochemistry, Vol. 95, Issue 21, 12220-12225 (August 1998).				
	C34	Jiang et al., "β-1, 3-Glucan recognition prote binds β-1, 3-Glucan and lipoteichoic acid to activation," <i>Insect Biochemistry and Molecu</i>	aggregate fungi and ba	acteria and stimulate prophenoloxidase		
	C35	Johansson et al., "Cellular Immunity in Crus 6 (1989).	taceans and the proPC	System," Parasitology Today., Vol. 5, No.		
	C36	Jolliffe et al., "The Energized Membrane and 763 (September 1981).	d Cellular Autolysis in	Bacillus subtilis," Cell, Vol. 25, pp. 753-		
	C37	Kawabata et al., "The Clotting Cascade and Crab," New Directions in Invertebrate Immu				
	C38	Kobayashi et al., "Detection of peptidoglyca Immunology and Medical Microbiology, 28:		ing the silkworm larvae plasma test," FEMS		
	C39	Lackie et al., "Invertebrate immunity," Para	sitology, 80: 393-412	(1980).		
	C40	C40 Loker et al., "On Being A Parasite in an Invertebrate Host: A Short Survival Course," J. Parasitol. 728-747 (1994).				
	C41	Mattsson et al., "Highly Purified Lipoteicho Activity and Tissue Factor Expression in Hu Comparision with Peptidoglycan," Infection	man Monocytes but Is	a Weak Inducer in Whole Blood:		
	C42	Morath et al., "Structural Decomposition and Infection and Immunity, pp. 938-944 (Februa		mmercial Lipoteichoic Acid Preparatiions,"		
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DATE CONSIDERED

EXAMINER

FORM	PTO –	1449	ATTORNEY DOCKET NO.: CHR-004				
			APPLICANT(S): Wainwright et al.				
INFO	RMA1	TION DISCLOSURE STATEMENT	SERIAL NO.: 10/803,177				
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EXAM. INIT.	ОТН	ER DOCUMENTS: (Including Author, Tit	e, Date, Relevant Pages, Place of Publication)				
	C43	Muta et al., "Limuls Factor C," Journal of B Baltimore, MD, Vol. 266, No. 10 pp. 6554-6	iological Chemistry, American Society of Biological Chemists - 561 (1991).				
	C44		ation and Prophenol Oxidase Activation in Arthropod Host try, Vol. 275, No. 38, pp. 29264-29267 (September 2000).				
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	C46	Nellaiappan et al., "On the Presence of Prophenoloxidase in the Hemolymph of the Horseshoe Crab," Limulus, Comp. Biochem. Physiol., Vol. 113B, No. 1, pp. 163-168 (1996).					
	C47	Obayashi et al., "A new chromogenic endoto enzymes and its clinical applications," Clin.	xin-specific assay using recombined limulus coagulation Chin. Acta 149:55-65 (1985).				
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	C49	Pearson <i>et al.</i> , "Comparison of Chemical An 8, No. 3:291-298 (1984).	alyses of Hollow-Fiber Dialyzer Extracts," Artificial Organs, V				
	C50		oxidase Cascade and Initiation of Nodule Formation in Locusts mental and Comparative Immunology, Vol. 15, pp. 33-39 (1991)				
	C51	Roslansky et al., "Sensitivity of Limulus Am Clinical Microbiology, Vol. 29, No. 11:247	ebocyte Lysate (LAL) to LAL-Reactive Glucans," Journal of -2483 (November 1991).				
	C52	, , , , ,	e in the Hemolymph of <u>Manduca Sexta</u> is Present in the Plasmand Comparative Immunology, Vo. 11, pp. 479-485 (1987).				
	C53	Seki et al., "Horseshoe Crab (1,3)-β-D-Gluc Chemistry, Vol. 269, No. 2:1370-1374 (Janu	an-sensitive Coagulation Factor G," <i>The Journal of Biological</i> ary 1994).				
	C54	C54 Shah <i>et al</i> , "A novel glucan-binding protein with lipase activity from the oral pathogen <i>Streptococcus</i> mutans," <i>Microbiology</i> , 150: 1947-1956 (2004).					
	C55 Söderhäll, "Prophenoloxidase Activating System and Melanization – A Recognition Mechanism of Arthropods? A Review.," Developmental and Comparative Immunology, Vol. 6, pp. 601-611 (1982).						
	C56	Söderhäll et al., "The Prophenoloxidase Act the New York Academy of Sciences, Vol. 712	vating System and its Role in Invertebrate Defence," Annals of pp. 155-161 (April 15, 1994).				
EXAMIN	VER	·	DATE CONSIDERED				

FORM :	PTO –	1449	ATTORNEY DOCK	KET NO.: CHR-004			
			APPLICANT(S):	Wainwright et al.			
INFO	RMA7	TION DISCLOSURE STATEMENT	SERIAL NO.:	10/803,177			
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		OTHER ART, JOURI	NAL ARTICLES, E	TC.			
EXAM. INIT.	ОТН	ER DOCUMENTS: (Including Author, Title	e, Date, Relevant Page	s, Place of Publication)			
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